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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,271	09/10/2001	George M Yousef	MTS3USA	2550

270 7590 05/17/2004

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EXAMINER	
QIAN, CELINE X	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,271	YOUSEF ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 47-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *53* is/are allowed.

6)☒ Claim(s) *33,47-51 and 54* is/are rejected.

7)☒ Claim(s) *52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/10/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 33, 47-54 are pending in the application.

This Office Action is in response to the Amendment filed on 1/15/04.

Response to Amendment

The objection to claim 44 is moot in light of Applicant's cancellation of the claim.

The rejection of claims 1, 32, 35-37, 39 and 44 under 35 U.S.C.112 1st paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claim 33 under 35 U.S.C. 1121st paragraph has been withdrawn in light of Applicant's amendment of the claim.

The rejection of claims 32, 35, 36, 39 and 44 under 35 U.S.C.112 2nd paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1, 32, 39 and 44 under 35 U.S.C. 102 (b) is moot in light of Applicant's cancellation of the claims.

The rejection of claim 33 under 35 U.S.C. 102 (b) has been withdrawn in light of Applicant's amendment of the claim.

The rejection of claims 35-37 under 35 U.S.C.103(a) is moot in light of Applicant's cancellation of the claims.

Claim 49 is rejected under 35 U.S.C.101 for reasons discussed below.

Claims 33, 47, 48, 50, 51 and 54 are rejected under 35 U.S.C.112 1st paragraph for reasons discussed below.

Claim 52 is objected to for reasons discussed below.

New Grounds of Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 49 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to a host cell comprising a genomic sequence of human KLKL2 gene, which is a product of nature. Therefore, it is not a statutory subject matter.

Claim Rejections - 35 USC § 112

Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 54 recites isolated nucleic acid molecule comprising specific nucleotide fragments from SEQ ID NO: 13. MPEP states "New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). The specification does not disclose these claimed fragments specifically. Therefore, they constitute new matter.

Claims 33, 47, 48, 50, 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified and isolated nucleic acid molecule comprising a nucleic acid sequence comprising the sequence of SEQ ID NO:13, a nucleic acid sequence 100%

complementary to said sequence, a nucleic acid molecule differs from SEQ ID NO:13 in codon sequences due to the degeneracy of the genetic code, a vector comprising said nucleic acid, a probe comprising said nucleic acid, does not reasonably provide enablement for a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:13, wherein T is U, a vector comprising said nucleic acid, a probe comprising said nucleic acid, a nucleic acid molecule differs from SEQ ID NO:13 in codon sequences due to the degeneracy of the genetic code, wherein T is replaced by U, or a composition comprising said nucleic acid molecule and a pharmaceutically acceptable carrier, excipient or diluent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

The nature of the invention

The claim is drawn to a purified and isolated nucleic acid molecule comprising the sequence of SEQ ID NO:13, a nucleic acid sequence comprising the sequence of SEQ ID NO:13 wherein, T is U, or a nucleic acid sequence 100% complementary to said sequences. The claims

are further drawn to a vector or a probe comprising said sequences, and a nucleic acid molecule differs from said sequences in codon sequences due to the degeneracy of the genetic code. Claim 51 is drawn to a composition comprising the nucleic acid molecule recited in claim 33 and pharmaceutically acceptable carrier, excipient or diluent, which implies that said composition has therapeutic effect.

The breadth of the claim and the teaching of the specification

The breadth of the claim encompasses both a DNA and a RNA represented by SEQ ID NO:13. The specification discloses that SEQ ID NO:13 is a genomic DNA sequence encoding KLK-L2 protein, and it is about 11.5kb in length. This gene encodes a polypeptide that consists 293 amino acid. However, the specification does not disclose a RNA sequence represented by the sequence of SEQ ID NO:13, in which the T is replaced with U. Further, the specification fails to teach a method to make the RNA represented by SEQ ID NO:13, or how to use such RNA molecule. Moreover, the specification fails to teach how to make a RNA with degeneracy codon in the coding sequence of such a RNA molecule. Nor does the specification teach a vector or probe comprising said RNA molecule. Lastly, the specification fails to teach any pharmaceutical composition comprising said nucleic acid molecule (both DNA and RNA). The breadth of the claim is thus broader than what is enabled by the instant specification.

The state of art and the level of predictability in the art

The prior art teaches that a genomic sequence encoding a protein comprises 5' or 3' regulatory region, introns and exons. Messenger RNA is transcribed from only exons of said genomic sequence, which skips the sequences from 5' or 3' regulatory region and introns. There is no RNA 100% complementary to a gene (genomic DNA sequence comprises 5' or 3'

regulatory region, introns and exons). Therefore, one skilled in the art would have to rely on the teaching of the specification to make and use the invention as claimed.

The specification only prophetically teaches a nucleic acid sequence represented by SEQ ID NO:13, in which T is replaced with U. The specification fails to teach how to make and use such RNA molecules. Further, the specification fails to teach how to make or use such RNA molecules as a vector or probe. Without such information, one skilled in the art would have to engage in undue experimentation to make and use the claimed invention.

The state of art at the time of filing does not recognize any correlation between a KLK-L2 gene and any disease. The specification also fails to teach what type of disease is linked with KLK-L2 gene or whether the nucleic acid encoding KLK-L2 has any therapeutic effect for any disease. As such, one skilled in the art would have to engage in undue experimentation to use the claimed nucleic acid molecule as a pharmaceutical composition. Therefore, the claims are not enabled for this embodiment.

Claim Objections

Claim 52 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot make references to two sets of claim to two different features. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim 53 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.